ARGUMENTS/REMARKS

Claims 1 and 31-75 are in the application.

Claim 1 is amended herein to correct "xylanol" to "xylenol". The same amendment is made to the specification at pages 5 and 7. This typographical error in the claims was originally noted by the Examiner in the Office Action mailed 25 October 2006.

Claims 1, 53 and 69 are amended to make the corrections noted in the Office Action.

Entry of this amendment, and reexamination and reconsideration of the application are respectfully requested in light of the foregoing amendments and the following remarks.

Rejection Under 35 USC §112, First Paragraph

Claims 1 and 31-75 stand rejected as lacking enabling disclosure. Applicants respectfully traverse this rejection for at least the following reasons.

As an initial matter, Applicants object to the timing of this rejection. This application has been pending since 2003 and there have been six Office Actions, and never once was this issue raised during that time. The previously pending claims were considerably broader than the claims now pending, but this issue was not raised at any time until now. Accordingly, Applicants consider that they have been prejudiced by the delay and failure to raise this issue until now, and request the rejection be withdrawn for that reason.

Despite the very untimely nature of this rejection, Applicants respond as follows.

Applicants respectfully submit that the present claims are fully supported by enabling disclosure in the specification. Both the organic sulfonate and the phenols specified in claim 1 are specifically exemplified in the examples I-XX at pp. 14-19 of the present application.

Contrary to the contention in the Office Action, the pending claims are not "extremely broad encompassing any and all compositions which may widely vary". The Examiner appears to contend that because the prior art failed to obtain the results disclosed and claimed in the present application, somehow the present invention is not fully enabled. As clearly shown by the Examples, the claimed combination obtains and provides the claimed goal. The fact that the prior art failed to attain the results only strengthens the present invention, showing both that the sought goal can be achieved and that it would not have

been obvious to have combined the ingredients recited in the presently pending claims. Far from evidencing a lack of enabling disclosure, the presently disclosed and claimed invention fully enables the skilled person to attain an improved result, as compared to the prior art.

The state of the prior art demonstrates that similar compositions have been used to attack and render harmless prions. The present invention provides another, improved method for attaining the same goal, i.e., attacking and rendering harmless prions.

Regarding the use of IFDO as a model rather than actually testing prions, the very same reference cited at page 4 of the Office Action, Burdon, J. Med. Microbiol., 29, p. 145-157 (1989), was cited in the present application at page 12, line 29 to page 13, line 21, with a full discussion of the accepted use of IFDO as such model. While IFDO is admittedly a model, it is the closest known model for use in studying agents for inactivating prions, and given the highly dangerous nature of prions, it is not unreasonable to employ a model rather than the actual, infectious agent. Use of a model does not mean there is or might be a lack of enabling disclosure.

The present application is replete with working examples. The examples I-XIV in the present application also compare the presently claimed invention using the claimed composition to a prior art process using of LpH™ and to similar compositions but with different phenols, and showed that the presently claimed invention is superior to the prior art process.

Regarding the contended lack of guidance in the specification, Applicants respectfully submit that the Examiner's reliance on lack of "guidance" regarding the actual structure of an IFDO and its relation to prions is misguided. The *Wands* factor relating to guidance has been fully met by Applicants numerous examples. It has been stated in the application that IFDO is a model for prions. Applicants have provided full guidance for how the invention is used against prions: all that need be done is for the body to be treated by the invention to be contaminated with prions instead of IFDO. *Wands* does not require that no experimentation be required, only that undue experimentation not be required. See *In re Wands*, 858 F.2d 731, 736-37 [8 USPQ2d 1400] (Fed. Cir. 1988). "The key word is

'undue,' not experimentation.'" *Id.* at 737. The specification need only teach those aspects of the invention that one skilled in the art could not figure out without undue experimentation. "Enablement is not precluded by the necessity for some experimentation such as routine screening." *Id.* at 736-737.

The same argument is applicable to the predictability factor. The mere fact that some experimentation would have to be carried out does not equate to a lack of enablement under *Wands*.

Finally, the amount of experimentation that would be necessary is relatively little, given Applicants plethora of working examples. The only experimentation that might arguably be needed would be to carry out the presently claimed invention on actual prions rather than the model IFDO. Everything else has been provided by the present application.

For all of the foregoing reasons, Applicants respectfully submit that the presently claimed invention is fully enabled in accordance with 35 USC §112, 1st paragraph, and accordingly Applicants respectfully request withdrawal of this ground of rejection.

Rejections Under 35 USC §103(a)

Claims 1, 31-40, 45-52 and 55-74 stand rejected under 35 U.S.C. §103(a) as unpatentable over Prusiner (US 6720355) and Ernst and Race (Ernst et al., "Comparative analysis of scrapie agent inactivation methods," *Journal of Virological Methods*, 41 (1993) 193-202). Claims 54 and 75 stand rejected as obvious over Prusiner and Ernst and Race, and further in view of Foster, (US 7252720). Claim 53 stands rejected as obvious over Prusiner and Ernst and Race, and further in view of McDonnell (US 7001873) and/or Narayanan (US 5326789).

Applicants respectfully traverse each of the foregoing rejections for at least the following reasons.

Since all of the rejections are based upon the basic combination of Prusiner and Ernst and Race, the focus of the following discussion is on this contended combination.

Prusiner discloses compositions for inactivating prions including, *inter alia*, alkyl sulfonate.

As admitted in the Office Action, Prusiner does not disclose (or suggest) a method using phenols of any kind. In fact, the word or root "phenol" does not appear at any point in Prusiner. There is nothing in Prusiner that would reasonably suggest that other known agents might be combined with the alkyl sulfonate.

Ernst and Race disclose compositions for inactivating prions including one designated LpH (the same as discussed above), which is disclosed to be an aqueous acid phenolic disinfectant which contains 12.6% glycolic acid, 3.0% *p*-tertiary amylphenol, 6.1% *o*-benzyl-*p*-chlorophenol, 0.5% 2-phenylphenol, <5% hexylene glycol, and <10% isopropanol by weight. The LpH formulation does not include the use of an organic sulfonate. Ernst and Race do not disclose anything that would constitute a suggestion or motivation to add an organic sulfonate or any other surfactant to the LpH formulation.

Ernst and Race is discussed in the Applicants' specification at page 4, lines 21-34 and is directly compared against Applicants' composition in the examples. Applicants' specification also contains examples showing formulations within the scope of the Applicants' claims 1 and 56, as compared to other phenol-based formulations outside the scope of the Applicants' claims 1 and 56.

In each instance, superior results were obtained when the formulations within the scope of the Applicants' claims 1 and 56 were used.

Specifically, the Examiner's attention is directed to Examples 1 and 2 of the Applicants' specification wherein formulations I-XX as well as the LpH formulation were tested using log reductions as the measure of efficacy of the tests. The test procedure is described in the Applicants' specification at page 12, line 27 to page 13, line 21. The log reduction values are measures of the effectiveness of a formulation for inactivating prions. The higher the log reduction value, the better the inactivation of prions. On page 15 at lines 5-6, the Applicants reported that the log reduction value for the LpH formulation was 4.0. The formulations I-XIV in Tables 1 and 2 on pages 15 and 16 are within the scope of the Applicants' claims 1 and 56, and for each of these formulations the log reduction value was higher than that for LpH, that is, the values for formulations I-XIV were in the range from 4.1 to 6.7. The value of 6.7 achieved for formulation VII indicated no visible colonies, since the

initial count was Log_{10} 6.7 per mL. On the other hand, in formulations XV-XX in Table 2 on page 17, which did not employ one or more of the phenols specified in the Applicants' claims 1 and 56 in combination with an organic sulfonate, the log reduction values for each of these were significantly lower, that is, in the range from 2.7-3.8. Thus, it is respectfully submitted that when one or more of the phenols specified in the Applicants' claims 1 and 56 are used in combination with an organic sulfonate, the log reduction values suggest an unexpected improvement over the prior art LpH formulation and the formulations XV-XX.

Thus, even if it might have been *prima facie* obvious to combine the sulfonate of Prusiner with a composition such as the LpH formulation, Applicants' examples show that an unexpected synergy is exhibited by the claimed combination, which could not have been expected based on the disclosures of the prior art.

Therefore, Applicants respectfully submit that this evidence, in the application examples, fully rebuts any possible *prima facie* case of obviousness.

For the foregoing reasons, Applicants respectfully submit that the presently claimed invention of claims 1 and 56, and the claims dependent thereon, would not have been obvious over Prusiner in view of Ernst and Race.

Claim 45 would not have been obvious for an additional reason: the Office Action fails to state a legally correct *prima facie* case of obviousness, since the rejection is supported by nothing more than speculation about what might have happened.

Claim 45 recites that at least one of the phenols in the combination of phenols has a Log P_c value of at least about 2.5. The Office Action, at page 9, contends that it would have been obvious to combine the teachings of Prusiner and Ernst and Race to include at least one phenol with a Log P_c value of at least about 2.5. This contention is completely unsupported in the Office Action by any citation to any disclosure that would have even suggested such a factor could possibly be important in selecting at least one phenol for inclusion in such a composition. The reference to the use of water would, if anything, teach away from the use of a phenol having a greater hydrophobicity, which is what Log P_c measures. Since the prior art uses an aqueous system, absent any teaching to the contrary, a person of ordinary skill would expect agents having greater hydrophilic nature,

not greater hydrophobic nature, to have been more effective. In the absence of any such teaching, and in the face of this teaching-away, Applicants respectfully submit that there is no factual support for this rejection.

Accordingly, for this reason, in addition to the reasons above for the base claim, Applicants respectfully submit that the invention described in claim 45 would not have been obvious over the contended combination of Prusiner and Ernst and Race.

Applicants respectfully submit that claim 1 would not have been obvious over the prior art cited by the Examiner. Claims 31-55 depend from amended claim 1 and would not have been obvious over the cited references for at least the same reasons that claim 1 would not have been over such references. Withdrawal of the rejection is believed to be warranted and is respectfully requested.

Applicants respectfully submit that claim 56 would not have been obvious over the prior art cited by the Examiner. Claims 57-75 depend from claim 56 and also would not have been obvious over the cited references for the same reasons. Withdrawal of the rejection is believed to be warranted and is respectfully requested.

Applicants respectfully submit that the application is in condition for allowance. A Notice of Allowance is respectfully requested.

Any additional fees required for the filing of this paper may be charged to Deposit Account No. 18-0988. In the event the Examiner would like to discuss any matter involving this application with the Applicants, he is invited to contact the undersigned attorney by telephone.

Respectfully submitted,

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